IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

WYETH,	*	
Plaintiff,	*	
v.	*	CIVIL NO.: WDQ-07-0632
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.	*	
Defendants.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

Wyeth sued Lupin Ltd. and Lupin Pharmaceuticals (collectively, "Lupin") for patent infringement of United States Patent No.'s 6,274,171 B1 (claims 20-25), 6,403,120 (claims 1 and 2), and 6,419,958 B2 (claims 1-6) under 35 U.S.C. § 271(e) ("Patents-in-Suit"). Pending are Wyeth's motion for summary judgment and Lupin's cross-motion for summary judgment. For the following reasons, the motions will be denied.

I. Background

The patents-in-suit form Effexor® XR, an extended release anti-depressant medication with venlafaxine hydrochloride as its active ingredient. Pl. Mot. Summ. J. Ex. 1 at Col. 2:20-28, 2:46-63, Ex. 2 at Col. 2:4-64, 10:35, Ex. 3 at Col. 2:48-64, 10:57.

The three Wyeth patents-in-suit have the same specification. Pl. Mot. Summ. J. Exs. 1, 2, 3. Eight of the claim terms in the

patents-in-suit are at issue in these Motions for summary judgment: (1) “An extended release formulation of venlafaxine hydrochloride,” Pl. Mot. Summ. J. Ex. 1 at Col. 10:59, Ex. 2 at Col. 10:35, Ex. 3 at Col. 11:2; (2) “a method for eliminating the troughs and peaks of drug concentration in a patient’s blood plasma,” Pl. Mot. Summ. J. Ex. 1 at Col. 13:4, Ex. 3 at 12:1; (3) “a method for providing a therapeutic blood plasma/drug concentration of venlafaxine over a twenty four hour period,” Pl. Mot. Summ. J. Ex. 1 at Col. 12:63, Ex. 2 at Col. 10:36, Ex. 3 at Col. 10:5; (4) “a method... that provides a peak blood plasma level of venlafaxine in from... about four to about eight hours,” Pl. Mot. Summ. J. Ex. 1 Col. 13:4, or “from about five to about eight hours,” *Id.* at Ex. 1 Col. 13:22, or “in about six hours,” *Id.* at Ex. 1 Col: 14:5; (5) “a method... that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml,” Pl. Mot. Summ. J. at Ex. 2 at Col. 10:36; (6) “diminished incidences of nausea and emesis” in comparison to immediate release Effexor®, Pl. Mot. Summ. J. Ex. 1 at Col. 12:63, Ex. 2 at Col. 10:36, Ex. 3 at Col. 10:57; (7) “patients in need thereof,” Pl. Mot. Summ. J. Ex. 1 at Col. 12:66; Ex. 2 at Col. 10:4; Ex. 3 at Col. 10:38; and (8) “encapsulated,” *See* Pl. Mot. Summ. J. Ex. 1 at Col. 12:67; Ex. 3 at Col. 10:44.

For claim construction purposes, the following claims are illustrative of how these terms are used. Claims 20 and 21 of

the ‘171 patent state:

> 20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 21. A method for eliminating the troughs and peaks of drug concentration in a patients [sic] blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

During the development of Effexor® XR, Deborah Sherman, a Wyeth employee, contacted Paul Shesky, an employee of Dow Chemical. Dow produces HPMC, which Sherman was working with in laboratory testing. Def. Mot. Summ. J. Ex. 6 at 256:12. Shesky gave Sherman advice as to which Dow products to use, given the experiment conditions described by Sherman. Def. Mot. Summ. J. Ex. 9 at WYETH 053-001351. One of Shesky’s suggested HPMC grades tested successfully, and Wyeth incorporated it into Effexor® XR. Def. Mot. Summ. J. Exs. 25, 38-41 and 60. Sherman was cited as an inventor of all three patents-in-suit, but Shesky was not. Pl. Mot. Summ. J. Exs. 1, 2, 3.

Lupin has applied for an Abbreviated new Drug Application

("ANDA") with the United States Food and Drug Administration ("FDA"). Def. Mot. Summ. J. Ex. 20. FDA approval will authorize Lupin to produce and sell a generic version of Effexor® XR.

On March 13, 2007, Wyeth sued Lupin for a declaratory judgment that the commercial manufacture, use, sale, or importation of Lupin's extended release venlafaxine hydrochloride product would infringe the patents-in-suit, and an injunction prohibiting FDA approval of Lupin's ANDA until the expiration of the patents-in-suit.

On April 2, 2007, Lupin answered Wyeth's Complaint and filed Counterclaims, seeking a declaration that its ANDA product does not, and will not, infringe any claims of the patents-in-suit. On September 11, 2007, the Court denied Lupin Pharmaceutical's motion to dismiss. On June 27, 2008, Wyeth filed a motion for partial summary judgment. On July 11, 2008, Lupin filed its motion for summary judgment.

II. Analysis

A. Standard of Review

Under Rule 56(c), summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v.*

Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The court must view the facts and reasonable inferences drawn therefrom "in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (*quoting United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) (per curiam)). The opposing party, however, must produce evidence upon which a reasonable fact finder could rely. *Celotex*, 477 U.S. at 324. A mere "scintilla" of evidence is insufficient to preclude summary judgment. *Anderson*, 477 U.S. at 252.

B. Patent Infringement Analysis

Patents are composed of two parts. The specification describes the invention and the manner and process of using it. 35 U.S.C. § 112. The claims define the scope of the invention and state which parts of the invention the patentee is entitled the right to exclude. 35 U.S.C. §112; *Phillips v. AWH Corp*., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc).

Infringement analysis entails two steps. The first step requires "claim construction," a determination of the "meaning and scope" of the patent claims alleged to be infringed. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc). Claim construction is a question of law. *Id.* at 978. The second step requires comparing the "properly construed claims to the device accused of infringing." *Id.* This is a question of

fact. To find infringement, every element of the patent must be infringed, either literally or under the doctrine of equivalents. *See Leggett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1358 (Fed. Cir. 2002)*; Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 25 (1997). "A claim element is equivalently present in an accused devices if only insubstantial differences distinguish the missing claim element from the corresponding aspects of the accused device." *Leggett & Platt, Inc.*, 285 F.3d at 1359 (*citing Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed Cir. 1997)).

When construing claims, the Court gives terms "the ordinary and customary meaning... that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313. A person of ordinary skill in the art is presumed to read the claim terms in light of the entire patent, including the specification. *Id.* Thus "the Court starts the decision making process by reviewing the... patent specification and the prosecution history." *Id.* The claim text and other claims in the patent also provide "substantial guidance" to the meaning of the terms, although the Federal Circuit cautions that the specification is the "best source for understanding a particular term." *Id* at 1314 - 1315.

To aid its claim construction, a court may look to publicly available sources that explain what a person skilled in the art

would understand the term to mean. *Id*. These sources include "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* Extrinsic evidence may include dictionaries, treatises, and expert testimony. *Id.* at 1317. Intrinsic evidence is favored over extrinsic evidence in claim construction. *Id.* at 1318.

C. Wyeth's Motion for Summary Judgment

Wyeth argues that Lupin's proposed generic drug infringes its patents-in-suit. Pl. Mot. Summ. J. Lupin asserts that Wyeth's claim construction is incorrect and, under proper construction, its product does not infringe the patents-in-suit. Def. Mot. Summ. J. at 32. Infringement requires a showing that every element of a patent is infringed, either literally or under the doctrine of equivalents. *See Leggett & Platt*, Inc., 285 F.3d at 1358. Because there are issues of material fact as to infringement of some of the claims in issue, summary judgment must be denied.

1. "Extended Release Formulation"

a. Construction

Wyeth alleges the claim "extended release formulation" should be construed to mean

> "[A] formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such

that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." Pl. Mot. Summ. J. at 15.

This was the construction given to the term in *Wyeth v. Impax Lab. Inc*., 526 F.Supp.2d 474, 480 (D. Del. 2007). In that case, Wyeth filed suit against Impax for infringement of the same patents at issue here. Unlike Lupin's arguments, Impax alleged that the term "extended release formulation" required specific inactive ingredients. Lupin instead argues that "extended release formulation" requires a spheroid formation, rather than specified ingredients.[1] The *Impax* court agreed with Wyeth that "extended release formulation" should not be construed to require specific ingredients, but did not touch on the issue of whether "extended release formulation" required spheroid form. *Id.*

The specifications for the patents-in-suit are the first source of information as to the ordinary meaning of "extended release formulation." *See Phillips*, 415 F.3d at 1315. The specification in the '171 Patent is representative of all three specifications at issue. As it is first defined in both the Brief Description and Detailed Description, the term "extended

[1] Lupin asserts that the term spheroid should be narrowly construed to exclude pellets, the shape it claims for its product. A full discussion of this argument begins on Page Eleven.

release formulation" is not modified by the term "spheroids."[2] Pl. Mot. Summ. J. Ex. 1 at Col. 2:15, Col. 4:9. Despite this, the specification uses "spheroid" with the term "extended release formula" throughout the remainder of the specification. Pl. Mot. Summ. J. Ex. 1 Col. 2:66, Col. 3:7, 4:13, 4:26, 5:13. As a result, the specification provides conflicting evidence as to the scope of the term "extended release formulation."

The prosecution histories also present conflicting evidence as to the scope of the term "extended release formulation." In one of the patent prosecutions, the patent examiner referred to the invention as spheroids. Def. Mot. Summ. J. Ex. 31 at WYETH 002-000492. At other points in the prosecution history, Wyeth asserts that its invention is not limited to spheroid forms, *id.* at WYETH 002-000520, and a patent examiner makes a similar statement in the prosecution history. Pl. Mot. Summ. J. Ex. 53 at WYETH 002-000718.

The conflicting evidence in the specification and prosecution histories is not resolved by the claims. None of the disputed claims contains the term "spheroid." Pl. Mot. Summ. J.

[2] An example of the broad nature with which the invention is described is found in the "Brief Description of the Invention." The Brief Description begins, "In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containig venlafaxine hydrochloride as the active drug's component, which provides in a single dose, a therapeutic blood serum level over a twenty four hour period." Pl. Mot. Summ. J. Ex. 1 at Col. 2:15.

Exs. 1, 2, 3. Undisputed claims mention spheroids in connection with "extended release formulation," however. *Id.* Under the theory of claim differentiation, claim construction which makes claims redundant is to be avoided. *See Honeywell Intern. Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982, 994 (Fed. Cir. 2007). However, claim differentiation is only a guideline. *See Liebel-Flarsheim Co. v. Medrad, Inc*., 358 F.3d 898, 910 (Fed. Cir. 2004). Claim differentiation is most persuasive when a dependent claim would be redundant if the disputed claim is constructed in a certain manner. *See Ecolab, Inc. v. Paraclipse, Inc*., 285 F.3d 1362, 1375 (Fed. Cir. 2002). Here, only one claim using the term "spheroid" is dependent on disputed claims which do not include the term.[3] That a dependent claim would be redundant under the narrower construction of "extended release formulation" does not bar the narrower construction.

Because the patent specification, prosecutions, and claims present conflicting guidance as to the proper construction of the term "extended release formulation," the narrower definition holds. *See Athletic Alternatives, Inc. v. Prince Mfg.*, Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996). Thus, "extended release

[3] None of the claims containing the term "spheroid" in either the '171 or '958 patent is dependent on the disputed claims. One claim in the '120 patent (claim 13) that uses the term "spheroid' is dependent on a disputed claim which does not use the term.

formulation" in the patents-in-suit is defined as a spheroid formulation containing venlafaxine hydrochloride as the active drug component, which provides, in a single dose, a therapeutically effective amount of venlafaxine over a 24 hour period."

b. Infringement

Although claim construction is a question of law, infringement is a question of fact. To find infringement, the fact finder must determine that every claim limitation or its equivalent is in the accused device. *In re Gabapentin*, 503 F.3d at 1259.

There is a genuine issue of material fact whether Lupin's product is a spheroid formulation. Wyeth asserts that a spheroid is one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round and may include granules, beads, and pellets. Pl. Mot. Summ. J. Ex. 7 at Ex. B ¶¶ 13-20. Lupin opposes equating spheroids with pellets. Pl. Rep., ex. 19 at Ex. A ¶¶ 31-32. Nothing in the claims, specifications, or patent files suggests either construction of "spheroid" is preferred. As the extrinsic evidence provides conflicting guidance, s*ee Id.*, Pl. Mot. Summ. J. Ex. 7 at Ex. B ¶¶ 13-20, the narrower construction of the claim is correct. Spheroids are one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round.

Lupin's tablets are generally round but are defined by parallel planes and have sharp edges. Def. Mot. Summ. J. Ex. 19 at Ex. A, ¶ 38. Lupin contends that the sharp edges preclude defining the tablets as spheroids. Def. Mot. Summ. J. at 34; Ex. 19 at Ex. A ¶ 43, Ex. B ¶¶ 20-25. Wyeth counters that the sharp edges and parallel planes do not preclude finding that the Lupin tablets are spheroids. Pl. Repl. at 29; Ex. 7 at Ex. B ¶¶ 18, 24. Whether this shape is a spheroid is a question for the factfinder.[4] Thus, summary judgment must be denied.

2. "A Method for Eliminating the Troughs and Peaks of Drug Concentration in a Patient's Blood Plasma"

a. Construction

Wyeth proposes that the term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" means

> "A method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide, during the course of treatment, relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine

[4] Lupin's experts state that its product is not a spheroid under the definition adopted by the Court. Def. Mot. Summ. J. Ex. 19 at Ex. A ¶ 38. Photographs of Lupin's product and Wyeth's product provide reasonable support for this assertion. *See* Def. Rep. at 11, Pl. Rep. at 30.

blood plasma concentration versus time."

Pl. Mot. Summ. J. Ex. 52 at 17.

This definition is supported by the specifications.[5] Lupin does not propose an alternative claim construction. Pl. Mot. Summ. J. The Court thus adopts this claim construction. *See Phillips*, 415 F.3d at 1315 (The specification is the primary basis for construing the claims) (internal citation omitted).

b. Infringement

Lupin contends that its product is comparable to Wyeth's. Pl Mot. Summ. J. Ex. 13 at LUP020777; Ex. 51 at 133:5-7. Lupin has not presented evidence creating a genuine issue on this claim at issue. *See* Pl. Mot. Summ. J. Thus, Lupin's product infringes the patents-in-suit on this claim.

3. "A Method for Providing a Therapeutic Blood/Drug Plasma Concentration of Venlafaxine Over a Twenty-Four Hour Period"

---

[5] The specification for the '171 Patent is demonstrative. It states, "through the administration of the venlafaxine formulation of this invention, there is provided a method for obtaining a flattened drug plasma concentration to time profile, thereby affording a tighter plasma therapeutic range control than can be obtained with multiple daily dosing... In essence, the plasma levels of venlafaxine Is [sic] hydrochloride rise, after administration of the extended release formulations of this invention, for about five to about eight hours... and then begin to fall through a protracted, substantially linear decrease from the peak plasma level for the remainder of the twenty four hour period, maintaining at least a threshold therapeutic level of the drug during the entire twenty-four hour period." Pl. Mot. Summ. J. Ex. 1 at Col. 2:20.

Wyeth argues that the term "a method for providing a therapeutic blood/drug plasma concentration of venlafaxine over a twenty-four hour period" means a level of venlafaxine in blood plasma that provides relief during the course of treatment. Pl. Rep. at 24.

Lupin argues that the proper construction of this term requires an expressly stated correlation between the terms venlafaxine and therapeutic.[6] Lupin argues that it is not venlafaxine, but a byproduct of venlafaxine ("ODV"), produced when the body metabolizes venlafaxine, that provides the therapeutic benefits the patents-in-suit associate with venlafaxine. Because of this, Lupin argues, Wyeth's proposed claim construction is incorrect. Def. Mot. Summ. J. at 55. As Wyeth notes, however, ODV is produced by the body upon intake of venlafaxine. Pl. Mot. Summ. J. Ex. 57 at 723. Because venlafaxine is the chemical necessary to produce the therapeutic effect -- whether ODV or venlafaxine causes the therapeutic effect -- Lupin's argument fails and Wyeth's construction of the term must be adopted.

The term will thus be construed to mean a level of venlafaxine in blood plasma that provides relief during the

[6] Lupin's proposed construction of the term is "a method for providing a therapeutic blood/drug plasma concentration of venlafaxine *alone* over a twenty-four hour period" (emphasis added).

course of treatment.

b. Infringement

Lupin does not deny that its higher dose tablet forms (75 mg and 150 mg tablets) infringe under the Court's construction of "therapeutic blood/drug plasma level." *See* Def. Mot. Summ. J. at 53. Thus Lupin's product infringes this claim.

4. "A Peak Blood Plasma Level of Venlafaxine in from:" "About 4 to about 8 hours," "about 5 to about 8 hours," and "about 6 hours"

a. Construction

Wyeth proposes the word "about" refers to a range based on rounding. Thus "about 4 hours to about 8 hours" would mean "a range, based on rounding, of 3.5 hours up to, but not including, 8.5 hours." Similarly, "about 5 to about 8 hours" would range from 4.5 hours to 8.5 hours. Pl. Mot. Summ. J. at 29.

Wyeth also proposes that the claim should be construed to refer to the time at which the maximum concentration of venlafaxine in an individual patient's blood plasmas is reached ("T_{max}" value). *Id.*

Lupin agrees that the times stated in the disputed claim refer to the T_{max} value. Def. Mot. Summ. J. at 37. Though, Lupin disagrees with Wyeth's assertion that the value refers to individual patients. Lupin argues that the T_{max} values refer to a group of subjects.

These claims refer to the peak therapeutic blood concentrations of individual patients.[7] The words of a claim are generally given their ordinary and customary meaning. *Phillips*, 415 F.3d at 1312 (internal citations omitted). In this case, however, the words "in a patient" refer to the individual expression of a numerical value culled from studies done on groups of subjects. As a result, the plain meaning of the claim terms does not lead to correct claim construction.

The correct understanding of the T_{max} (and C_{max}) values referenced in the claims is that those values refer to an average value taken from multiple individuals. Although the claims refer to individual patients, the numerical values that the claims reference are based on studies done on more than one individual, as explained by the specifications. Tables Two and Three and the corresponding written explanations describe Wyeth's studies of the T_{max} of the invention reference "human male subjects" and present numbers that are based on the aggregation of the results of multiple individuals. Def. Mot. Summ. J. at 45; Pl. Mot. Summ. J. Ex. 1 Col. 7:29-67. The

[7] For example, Claim 20 of the '171 Patent states, "A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to *a patient* in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in about 4 to about 8 hours..." Pl. Mot. Summ. J. Ex. 1, Col. 12:63 (emphasis added).

specification does not present evidence of T_{max} values of individual patients. As a result, the claim must be read to reference values taken from more than one person.

b. Infringement

An accused product that sometimes, but not always, embodies a claimed method nonetheless infringes. *Bell Commc'n Research Inc. v. Vitalink Communications*, 55 F.3d 615, 623 (Fed. Cir. 1995). Lupin's test data drawn from multiple human subjects show that its product infringes the claim in question by achieving a T_{max} value within the designated time. Pl. Mot. Summ. J. Ex. 34 at LUP000814. Lupin's product therefore infringes this claim of the patents-in-suit.

5. "That Provides Peak Blood Plasma Levels of Venlafaxine of No More Than About 150 ng/ml"

a. Construction

Wyeth and Lupin agree that this claim term refers to the maximum blood plasma concentration ("C_{max}") of venlafaxine in patients treated with extended release venlafaxine formulations. Pl. Mot. Summ. J. at 30, Def. Mot. Summ. J. at 45.

Wyeth argues that the term "about" means an approximation, implying a range of values is appropriate. Pl. Mot. Summ. J. at 30. Wyeth asserts that the range should include 20 percent variation from the 150 ng/ml figure. *Id.* at 31; Ex. 19 at 14. Lupin agrees that the term "about" signals an approximation, but

argues that specification ambiguity makes it impossible to determine the acceptable range of C_{max} values that is appropriate to allow within the approximation implied by the term. Def. Mot. Summ. J. at 51; Ex. 33 ¶ 31; Ex. 34 at Ex. A. ¶ 21. Alternatively, Lupin argues that the term refers to experimental variability of ten percent or less. Def. Mot. Summ. J. Ex. 33 at Ex. A ¶ 31.

The term "about" is a "descriptive term commonly used in patent claims to avoid a strict numerical boundary to the specified parameter." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002). This does not mean however, that the scope is indefinitely vague. Rather, the scope attributed to "about" is that which a person skilled in the art would understand the range to be. *Id.*

Neither the claim language nor the specification sheds light on the range a person skilled in the art would attribute to the term "about" in this context. The extrinsic evidence is also conflicting. When there is a choice of construction, the narrower meaning of a claim controls. *Athletic Alternatives, Inc. v. Prince Mfg*., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996). Thus, Lupin's expert opinion that the term "about" indicates a ten percent variation of experimental variability in the claim "that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml."

b. Infringement

Lupin acknowledges that its product tests within the construed C_{max} range. Def. Mot. Summ. J. Ex. 43 at LUP000825-832. This requires a finding of infringement, despite the recognition that Lupin's product does not always test within the construed understanding of the C_{max} value. *See Bell Commc'n Research Inc.*, 55 F.3d at 623.

6. "Diminished Incidences of Nausea and Emesis"

a. Construction

Wyeth asserts the term "diminished incidences of nausea and emesis" means

> "The degree and/or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients recieving the same total daily dose of an immediate release formulation that is administered at least twice a day."

Pl. Mot. Summ. J. at 32.

Lupin counters that the term should be read to mean that the number of incidents of nausea and emesis is less than that experienced with the immediate release formulation, but not that the severity of those symptoms is decreased. Def. Mot. Summ. J. at 66.

The Court agrees with Wyeth's construction of the term. As noted in *Impax*, the patents-in-suit refer to "diminished incidences" only in the claims. *Impax*, 526 F.Supp. at 481; Pl. Mot. Summ. J. Ex. 1. Nausea and emesis are discussed in the

specification with reference to “lower incidences,” “reduc[tion] by adaptatation,” and “reduc[tion] [of] the level of nausea and incidence of emesis.” *Id.* at Abstract, Col. 2:47. None of these phrases suggests that the focus should be only the number of incidences. The term “level” strongly suggests severity rather than numbers. As the *Impax* Court also noted, if the inventors had intended the claim to refer to numbers of instances of nausea and/or emesis, they would have chosen terminology that more clearly suggests numbers rather than implies degree. *Wyeth v. Impax*, 526 F.Supp. at 482. By using “level” and “diminished” over words like “fewer,” the Wyeth inventors ensured the claims would cover both a reduction in the number of incidences of nausea/emesis and a reduction in the degree of severity of those side effects.

b. Infringement

Infringement is a factual question. Wyeth asserts that its product has diminished incidences of nausea and emesis when compared to its Effexor® predecessor and that Lupin claims a similar decrease for its product in its ANDA application. Pl. Mot. Summ. J. Ex. 8 at Ex. A, 12, 19; Ex. 39 at WYETH 004-019562, 004-019563; Ex. 6 at Ex. A, 15-18; Ex. 34 at LUP000786; Ex. 35 at LUP003511.

Lupin asserts that Wyeth has failed to show that patents-in-suit properly claim diminished incidences of nausea and

emesis, arguing that the data instead shows no "statistically significant difference" in levels of nausea between the dosage forms, and that Lupin's bioequivilant product therefore also shows no statistically significant difference from the immediate release version of Effexor®. Def. Mot. Summ. J. Ex. 33 at Ex. A ¶ 47; Ex. 56 at WYETH 004-004421; Ex. 57 at WYETH 012-001904.

There are genuine issues of material fact with regards to whether the patents-in-suit cause diminished incidents of nausea and emesis.

7. "Patient In Need Thereof"

a. Construction

Lupin asserts "patient in need thereof" refers only to patients suffering from depression. Def. Mot. Summ. J. at 53. Wyeth argues instead that the term refers to any patient who, as of the date of the patent application, could be treated with an anti-depressant. Pl. Resp. at 26.

The specification is unhelpful in determining which construction is correct. The Abstract describes the active ingredient as an antidepressant, which supports Wyeth's broad reading of the term. Pl. Mot. Summ. J. Ex. 1. The Background of the Invention, however, states that the active ingredient is "used for the treatment of depression." *Id.* Col. 1: 61. This supports Lupin's construction of the term. When construing claim terms, the Court must inquire how the term would be read

by a person of ordinary skill in the art. *Phillips*, 415 F.3d at 1313. In this case, a person of ordinary skill in the art would have known at the date of patent filing that antidepressants are used to treat conditions other than depression. Pl. Resp. Ex. 8 at Ex. B, 35. As a result, the term "patient in need thereof" should not be limited to individuals suffering from depression and should instead be construed to include individuals suffering from conditions known to be relieved by antidepressants at the time the patent application was filed.

8. "Encapsulated"

Claims 20-25 of the '171 patent and Claim 2 of the '120 patent use the term "encapsulated." Lupin does not dispute that its product is formulated as a "capsule." *See* Def. Mot. Summ. J. Ex. 18 at LUP021005, LUP021061, LUP021073.

C. Lupin's Motion for Summary Judgment

Lupin argues that the patents-in-suit are invalid for failure to name a joint inventor, ambiguity, and failure to have possession of the invention at the time the patents-in-suit were filed. Alternatively, Lupin argues that its product does not infringe the patents-in-suit.

1. Failure to Name a Joint Inventor

A patent is invalid if it fails to name a joint inventor. 35 U.S.C. § 102(f). A joint inventor must contribute in "some significant manner" to the development of the invention and must

do more than explain to the inventor the current state of the art. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998); *Hess v. Advanced Cardiovascular Systems, Inc.*, 106 F.3d 976, 981 (Fed. Cir. 1997).

Lupin argues that the patents-in-suit are invalid because they fail to identify Paul Shesky as an inventor. Def. Mot. Summ. J. at 19. Wyeth argues that Shesky was not an inventor and the patents are therefore valid. It is undisputed that a Wyeth scientist contacted Shesky with questions during her development of the patented inventions. Def. Mot. Summ. J. Ex. 9 WYETH 053-001351-52. Lupin contends that Shesky's answers to her questions were critical to the development process and that Shesky is therefore an inventor. Def. Mot. Summ. J. Ex. 10, ¶ 54-61, Ex. 14, 33:17-22. Wyeth asserts that Shesky was given minimal information about the developing inventions and acted only as a salesman of publicly available Dow products, not as a co-inventor. Def. Mot. Summ. J. Ex. 12, 54:6-9, Ex. 9 at WYETH 053-001351; Ex. 12, 54:6-10.

Because there is genuine issue of material fact as to Shesky's contribution to the patents-in-suits, summary judgment on this claim must be denied.

2. Invalid for Ambiguity

a. "Extended Release Formulation"

Because the Court adopts Lupin's narrow construction of the

term “extended release formulation,” Lupin’s argument that a broader reading of the term is indefinite is moot.

b. “A Method for Providing A Therapeutic Drug Concentration of Venlafaxine Over a Twenty-Four Hour Period”

Lupin argues that the claim term “a method for providing a therapeutic drug concentration of venlafaxine over a twenty-four hour period” is too vague for a member of the public to determine the scope of Wyeth’s patents and therefore is invalid under 35 U.S.C. § 112, ¶ 2 (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention”).

When the patent applications were filed, the amount of venlafaxine needed to provide a “therapeutic drug concentration” was unknown. Def. Mot. Summ. J. Ex. 10 at Ex. 5, LUP067596. Nor was it clear whether venlafaxine or its subsidiary byproduct, ODV, that provided the therapeutic relief. Def. Mot. Summ. J. Ex. 55. For these reasons, Lupin argues that the term is indefinite and invalid.

There are issues of fact whether “a method for providing a therapeutic drug concentration of venlafaxine over a twenty-four hour period” is invalid for vagueness, however. Wyeth proffers evidence that precise blood plasma concentration measurements

are not procured for psychiatric drugs. Pl. Resp. Ex. 8 at Ex. B, 25; Def. Mot. Summ. J. Ex. 10 at Ex. 5 LUP067596. If this is correct, then a person skilled in the art would understand the parameters of the claim term when read in the context of the specification. *See Marley Mouldings Ltd. v. Mikron Indus*., 417 F.3d, 1359 (Fed. Cir. 2005). Wyeth additionally cites Lupin's patent applications for extended release compositions of venlafaxine to argue against a finding of vagueness. Lupin's patent applications use the language it claims is void for vagueness, "providing a therapeutic blood plasma concentration of Venlafaxine." Pl. Resp. Ex. 99 at LUP029119. It seems unlikely, Wyeth argues, that Lupin would use indefinite language in its own patent application. The Court agrees. A triable issue exists whether the term "a method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period" is indefinably vague.

c. Cmax and Tmax Values

Lupin argues the specifications present insufficient evidence for replicating Wyeth's studies that resulted in the T_{max} and C_{max} values reported in the patent. Def. Mot. Summ. J. at 48, Ex. 33 at Ex. A ¶¶ 15-38; Ex. 34 at Ex. A ¶¶ 15-22; Ex. 36 ¶¶ 20-24, 28-34. Wyeth counters that the specifications present adequate information to satisfy §112's requirements of clarity. Pl. Repl. at 40, Ex. 1 Col. 8:64; Def. Ex. Because of

the factual nature of this dispute, summary judgment on the invalidity of the claims and the resulting issue of infringement must be denied.

3. Possession of the Claimed Invention at the Time the Patents-In-Suit Were Filed

Lupin argues that the patents-in-suit are invalid under 35 U.S.C. § 112, ¶ 1. Section 112 requires a written description of the invention sufficient to convey to a person of ordinary skill in the art that the inventor possessed the invention at the time the he filed the patent application. *Id.* Lupin argues that Wyeth did not have possession of the invention at the time the patents-in-suit were filed because Wyeth did not know the therapeutic blood/drug plasma concentration of venlafaxine at that time.

As discussed above, there are genuine issues of material fact whether an exact numerical value is required for the term "therapeutic blood/drug plasma concentration," and if an amount is required, what the numerical value would be. As a result, summary judgment on this claim must be denied.

4. Lupin's 37.5 mg Tablet Product

Lupin's ANDA application presents several versions of its generic extended release venlafaxine tablet, varied by dosing amount per tablet. Def. Mot. Summ. J. Ex. 20 at LUP008795. argues that its 37.5 mg tablet product, the lowest dosing amount

it seeks to produce, does not infringe the patents-in-suit. Pl. Mot. Summ. J. at 63. Lupin argues that 37.5 mg is an insufficient amount of venlafaxine to produce therapeutic results.

Wyeth literature suggests starting patients on 37.5 mg doses of their extended release venlafaxine product to allow for adjustment to the medication before increasing the dosing to 75 mg/day, with a maximum daily dose of 225 mg/day. Def. Mot. Summ. J. Ex. 16.; Pl. Mot. Summ. J. Ex. 8 at Ex. A at 21.

Wyeth argues that 37.5 mg of venlafaxine is sufficient to produce therapeutic results in certain patients. Alternatively, Wyeth argues that Lupin would market its 37.5 mg tablet as a two-pills-a-day product to facilitate its therapeutic benefits if it were found to be non-infringing. Pl. Repl. at 25; Pl. Mot. Summ. J. Ex. 11 at WYETH 301-00005; WYETH 301-000041; WYETH 301-000042; WYETH 301-000025.

Because there are material issues of fact on this issue, summary judgment must be denied.

III. Conclusion

For the above stated reasons, Wyeth's motion for summary judgment and Lupin's motion for summary judgment will be denied.

September 29, 2008
Date

/s/
William D. Quarles, Jr.
United States District Judge